

### REMARKS

After entry of this amendment, claims 1-13 and 25-38 will be pending for the Examiner's review and consideration. Claims 14-24 were previously withdrawn from consideration as being directed to a non-elected species until such time as a generic claim is held allowable. The Office Action dated April 25, 2004 has been carefully considered. The Applicant would first like to thank the Examiner for the allowance of claims 9-13, 25-28 and 36. Claims 1, 29, 37, and 38 have been amended. No new matter has been added. Reconsideration and allowance of the present application in view of the above amendments and the following remarks is respectfully requested.

In the Office Action dated April 25, 2004, the Examiner:

- rejected claims 1, 3, and 37 under 35 U.S.C. §102(b) as being anticipated by International Publication WO 99/39757 to Boyce *et al.* ("Boyce");
- rejected claims 2-8, 29-35, and 38 under 35 U.S.C. §103(a) as being unpatentable over Boyce in view of United States Patent No. 6,090,998 to Grooms *et al.* ("Grooms"); and
- allowed claims 9-13, 25-28 and 26.

### Independent Claim 1

Independent claim 1 has been rejected under 35 U.S.C. § 102(b) as being anticipated by Boyce. Independent claim 1, as amended, recites, *inter alia*, a bone sheet for implantation, the sheet having a top surface, a bottom surface and a plurality of side surfaces extending therebetween, the sheet further comprising an at least partially demineralized field substantially surrounding at least one mineralized region, wherein the at least one mineralized region extends from the top surface to the bottom surface. It is respectfully submitted, that Boyce does not disclose, teach, or suggest a bone sheet having an at least partially demineralized field substantially surrounding at least one mineralized region, wherein the at least one mineralized region extends from the top surface to the bottom surface. Rather, Boyce discloses a bone-derived sheet 21 having a fully or partially demineralized outer surface fully encircling or encapsulating a nondemineralized or partially demineralized core 22. There is absolutely no disclosure, teaching, or suggestion of a bone sheet having an at least partially demineralized field substantially surrounding at least one mineralized region, wherein the at least one mineralized region extends from the top surface to the bottom

surface. Therefore, it is respectfully submitted that the cited prior art does not disclose, teach, or suggest all of the limitations of independent claim 1. Thus, it is respectfully submitted that independent claim 1 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 1 is therefore respectfully requested.

Claims 2-8 all ultimately depend from independent claim 1, and thus, it is respectfully submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 2-8 is therefore respectfully requested.

#### Independent Claim 29

Independent claim 29 has been rejected under U.S.C. §103(a) as being unpatentable over Boyce in view of Grooms. Independent claim 29, as amended, recites, *inter alia*, a bone sheet for implantation, the sheet having a top surface, a bottom surface, and a plurality of side surfaces, the sheet further comprising a flexible and at least partially demineralized field extending from the top surface to the bottom surface; at least one mineralized region extending from the top surface to the bottom surface, the at least one mineralized region being substantially surrounded by the at least partially demineralized field; and at least one hole configured and dimensioned to receive at least one fastener. It is respectfully submitted, that Boyce does not disclose, teach, or suggest a bone sheet having a top surface and a bottom surface, the sheet further comprising a flexible and at least partially demineralized field extending from the top surface to the bottom surface and at least one mineralized region extending from the top surface to the bottom surface, the at least one mineralized region being substantially surrounded by the at least partially demineralized field. Rather, as previously stated, Boyce discloses a bone-derived sheet 21 having a fully or partially demineralized outer surface fully encircling or encapsulating a nondemineralized or partially demineralized core 22. There is absolutely no disclosure, teaching, or suggestion of a bone sheet having a flexible and at least partially demineralized field extending from the top surface to the bottom surface and at least one mineralized region extending from the top surface to the bottom surface, the at least one mineralized region being substantially surrounded by the at least partially demineralized field.

Furthermore, it is respectfully submitted that Grooms does not rectify the shortcomings of Boyce. More specifically Grooms also does not teach, disclose, or suggest a bone sheet having a top surface and a bottom surface, the sheet further comprising a flexible and at least partially demineralized field extending from the top surface to the bottom surface and at least one mineralized region extending from the top surface to the bottom surface, the

at least one mineralized region being substantially surrounded by the at least partially demineralized field. Rather, Grooms discloses an implant having at least one rigid, mineralized bone segment which is adjacent to and which transitions into a flexible, demineralized section.

Therefore, it is respectfully submitted that neither Boyce or Grooms, either alone or in combination, discloses, teaches, or suggests all of the limitations of independent claim 29. Thus, it is respectfully submitted that independent claim 29 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 29 is therefore respectfully requested.

Claims 30-35 all ultimately depend from independent claim 29, and thus, it is respectfully submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 30-35 is therefore respectfully requested.

#### Independent Claim 37

Independent claim 37 has been rejected under 35 U.S.C. § 102(b) as being anticipated by Boyce. Independent claim 37, as amended, recites, *inter alia*, a bone sheet for implantation, the sheet having a top surface, a bottom surface and a plurality of side surfaces, the bone sheet further comprising an at least partially demineralized field and at least one mineralized region having a mineralized top surface, a mineralized bottom surface, and at least one side surface; wherein the at least one mineralized region extends from the top surface to the bottom surface and is substantially surrounded by the at least partially demineralized field along the least one side surface. It is respectfully submitted, that Boyce does not disclose, teach, or suggest a bone sheet having a top surface and a bottom surface, the bone sheet further comprising an at least partially demineralized field and at least one mineralized region having a mineralized top surface, a mineralized bottom surface, and at least one side surface; wherein the at least one mineralized region extends from the top surface to the bottom surface and is substantially surrounded by the at least partially demineralized field along the least one side surface. Rather, as previously stated above, Boyce discloses a bone-derived sheet 21 having a fully or partially demineralized outer surface fully encircling or encapsulating a nondemineralized or partially demineralized core 22. There is absolutely no disclosure, teaching, or suggestion of a bone sheet having an at least partially demineralized field and at least one mineralized region wherein the at least one mineralized region extends from the top surface to the bottom surface and is substantially surrounded by the at least partially demineralized field along the least one side surface.

Therefore, it is respectfully submitted that the cited prior art does not disclose, teach, or suggest all of the limitations of independent claim 37. Thus, it is respectfully submitted that independent claim 37 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 37 is therefore respectfully requested.

#### **Independent Claim 38**

Independent claim 38 has been rejected under U.S.C. §103(a) as being unpatentable over Boyce in view of Grooms. Independent claim 38, as amended, recites, *inter alia*, a bone sheet for implantation, the sheet having a top surface, a bottom surface, and a plurality of side surfaces, the sheet further comprising a flexible and at least partially demineralized field; at least one mineralized region having a mineralized top surface, a mineralized bottom surface, and at least one mineralized side surface, wherein the mineralized region extends from the top surface to the bottom surface and the mineralized side surface is substantially surrounded by the at least partially demineralized field. It is respectfully submitted, that Boyce does not disclose, teach, or suggest a bone sheet having a top surface and a bottom surface, the sheet further comprising a flexible and at least partially demineralized field and at least one mineralized region having a mineralized top surface, a mineralized bottom surface, and at least one mineralized side surface, wherein the mineralized region extends from the top surface to the bottom surface and the mineralized side surface is substantially surrounded by the at least partially demineralized field. Rather, as previously stated, Boyce discloses a bone-derived sheet 21 having a fully or partially demineralized outer surface fully encircling or encapsulating a nondemineralized or partially demineralized core 22. There is absolutely no disclosure, teaching, or suggestion of a bone sheet having a flexible and at least partially demineralized field and at least one mineralized region, wherein the mineralized region extends from the top surface to the bottom surface and the mineralized side surface is substantially surrounded by the at least partially demineralized field.

Furthermore, it is respectfully submitted that Grooms does not rectify the shortcomings of Boyce. More specifically Grooms also does not teach, disclose, or suggest a bone sheet having a flexible and at least partially demineralized field and at least one mineralized region, wherein the mineralized region extends from the top surface to the bottom surface and the mineralized side surface is substantially surrounded by the at least partially demineralized field. Rather, as previously stated, Grooms discloses an implant

having at least one rigid, mineralized bone segment which is adjacent to and which transitions into a flexible, demineralized section.

Therefore, it is respectfully submitted that neither Boyce or Grooms, either alone or in combination, discloses, teaches, or suggests all of the limitations of independent claim 38. Thus, it is respectfully submitted that independent claim 38 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 38 is therefore respectfully requested.

In light of the above amendments and remarks, it is respectfully submitted that claims 1-13 and 25-38 are now in condition for allowance, and the Examiner is respectfully requested to reconsider this application with a view towards allowance. The Examiner is invited to call the undersigned attorney at 212-326-7883, if a telephone call could help resolve any remaining issues.

Date: June 25, 2004

Respectfully submitted,

  
By: Giuseppe Molaro

52,039

(Reg. No.)

For: Brian M. Rothery

JONES DAY

222 East 41st Street

New York, New York 10017

(212) 326-3939

35,340

(Reg. No.)